December 27, 2019

Landauer
% Mr. Matt Ennis
Quality Manager
2 Science Road
GLENWOOD IL 60425

Re: K192196
Trade/Device Name: microSTARii Medical Dosimetry System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: October 8, 2019
Received: October 16, 2019

Dear Mr. Ennis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS)

regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192196

Device Name
microSTARii Medical Dosimetry System

Indications for Use *(Describe)*
The LANDAUER® microSTAR®ii Medical Dosimetry System provides an accurate, reliable and easy-to-use dosimeter and reader intended for use in measuring dose on-phantom or on-patient in medical dosimetry applications, such as radiotherapy and diagnostic radiology. When used to measure patient dose, the system is used to provide a secondary verification of radiation dose as a means of Quality Control for the primary dose calculation method. The output of the microSTAR®ii system is not used to adjust the dose to the patient.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Submission Date: August 5, 2019

Submitter Information:

Submitted By: Moe Khosravi, Regulatory Affairs & Quality Director
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Device Information:

Trade Name: microSTAR®ii Medical Dosimetry System

Common Name: Dosimetry System

Classification Name: 21 CFR 892.5050 Medical Charged-particle radiation therapy system

Device Classification: Class II

Product Code: IYE

Predicate Device(s): Portable Dosimeter, K092285
Best Medical Canada, Ltd.
Class II,
Product Code IYE
21 CFR 892.5050 Medical Charged-particle radiation therapy system

Device Description: The LANDAUER® microSTARii Medical Dosimetry System consists of the following components to provide secondary verification of dose from various radiotherapy and diagnostic imaging devices:

- Dosimeter (nanoDot) to record radiation during radiation exposure.
- Reading device (microSTARii Reader) for reading the radiation dose recorded by the dosimeter.
- microSTARii Software Application, a simple software tool that the user interacts with for radiation dose calculation, dose reporting, managing and storing data.
- 2D barcode scanner.
- Calibration Dosimeter Set (nanoDots) for QC/Calibration.

Indications for Use:

The LANDAUER® microSTAR®ii Medical Dosimetry System provides an accurate, reliable and easy-to-use dosimeter and reader intended for use in measuring dose on-phantom or on-patient in medical dosimetry applications, such as radiotherapy and diagnostic radiology. When used to measure patient dose, the system is used to provide a secondary verification of radiation dose as a means of Quality Control for the primary dose calculation method. The output of the microSTAR®ii system is not used to adjust the dose to the patient.

Comparison to Predicate:

Though the indications for use are slightly different from the predicate, the intended use remains the same between the proposed device and predicate device (capturing and displaying radiation dose) and the proposed differences in indications are for clarity and do not have impact on safety or effectiveness. The microSTARii system utilizes OSL (optically-stimulated luminescence) dosimeters whereas the predicate utilizes MOSFET (Si-based metal-oxide-semiconductor field-effect transistor) dosimeters.

The proposed device employs the same fundamental scientific technology and these technological differences do not raise different questions of safety or effectiveness.

Performance Testing:

Non-Clinical:

No mandatory performance standards have been established for this device (Section 514 of the Act). The following testing was conducted to support the substantial equivalence of the proposed device to the predicate:

- Software testing was conducted to verify performance in accordance with FDA's guidance document entitled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."
- FDA's guidance entitled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices", dated October 2, 2014 was utilized.
- Electrical Safety (IEC 61010-1, Ed 3.1, 2017-01)

- Electromagnetic Compatibility (IEC 61326-1:2012)
- Performance (Bench) Testing, including:
  - Burn in / Intrinsic measurement
  - Light leakage
  - Repeatability Testing: Moving / Stationary
  - Calibration Factor
  - Linearity-QC Accuracy
  - LLD-Strong / LLD-Weak

Clinical:	Clinical testing was not necessary to support substantial equivalence of the proposed device to the predicate device.
Conclusion:	The above testing supports that the proposed device is as safe, effective and performs as well or better than the legally marketed predicate in its intended use. Therefore, the proposed device is substantially equivalent to the predicate.